REMARKS/ARGUMENTS

Reconsideration of this application is requested. Claims 9-11 remain pending in the application subsequent to entry of this Amendment. Responsive to the examiner's comments regarding the specification, applicant is requested to up-date the status information for the parent application. Instructions have been provided above for making this up-date.

Responsive to the examiner's request, a Brief Description of the Drawings is provided prepared on the basis of the discussions of the Figures in Examples 1 – 3 and the legends on the drawings themselves. Accordingly, no new matter is introduced.

On page 2 of the Official Action the examiner discusses applicants' claim for benefit of priority and asserts that priority is not accorded to prior application Serial No. 10/137,699. This determination is not pertinent to the remaining portions of the examination in that the prior art cited and relied upon was published in 1985 long before the filing date of the parent application. The availability of the cited document as prior art is not contested (the content and relevance of the document of course is contested, for the reasons expressed below).

Applicants also disagree with the examiner's position with respect to their claim for benefit of priority and while not controlling for other issues raised in the outstanding Official Action do wish to address the examiner's comments.

Independent claim 9 is directed to the treatment of uveitis, which is an autoimmune disease. The priority application provides a comprehensive support for autoimmune diseases and gives some specific examples of such diseases: multiple sclerosis, lupus erythematosus systemicus and rheumatoid arthritis.

Uveitis is a further example of an autoimmune disease, which was included in the International application PCT/IT03/00237, claiming priority of parent application 10/137,699. Therefore, the subject application is directed to a specific embodiment of the parent application, but it relates to the same invention, hence priority should be acknowledged.

In general, there is no need to find specific support in a parent application for a subsequent example of carrying out the invention. In the parent application, the generic term autoimmune disease was embodied in three different examples: multiple sclerosis, lupus and arthritis. No questions were raised on the basic concept of the invention. Therefore, the claimed priority must be granted for a further example of the same invention.

There are two prior art-based rejections. The first, stated on page 3, is one of alleged anticipation directed towards claims 9 and 10, it being argued that the cited document is pertinent in that it teaches the administration of an identical active agent to a host in need thereof using applicants' claimed method steps. The manner in which this document is applied is incorrect for the reasons given in support of the rejection fail to take into account important aspects of any therapeutic procedure or treatment -- beneficial results. The question is, is the object of the procedure beneficial to the patient. Method of treatment claims should not be viewed in isolation of the objective.

Applicants have some difficulties in following Examiner's reasoning.

First, the Examiner, in a previous section of the Office Action, does not recognize Applicant's right to priority because the parent application allegedly fails to provide sufficient support and enablement for uveitis.

Next, the Examiner states that the present claims 9 and 10 are anticipated by Mistrello et al. Applicant cannot see where Mistrello et al. provides support and enablement for treating uveitis. To be applied as prior art, the document must provide an enabling disclosure for the purpose it is cited and applied.

Applicants do not see a description of any uveitis treatment in Mistrello et al.

The reasoning in the current Action is contradictory: *see* the statement on page 3, of the Office Action, last paragraph of point 1 where the theory of inherency is applied in reading the prior art. Thus, Applicants question why the same theory of inherency is not adopted in reading the priority application. In our view, the same reading should be adopted in evaluating the invention over the prior art.

In any event, Mistrello et al. published in 1985 is available as prior art.

This reference was discussed in the parent case and the arguments are relied on also for the present case. Mistrello et al. give a very generic teaching on the immunosuppressive activity of the compound used in the method of the present invention, and it will be observed that the compound proved to be *in*effective in the treatment of arthritis. Further, Mistrello et al. show that the compound *is* effective in heterologous skin transplantation, which is not an autoimmune disease. Therefore, Mistrello et al. do not disclose autoimmune diseases and in any case, a

generic disclosure (autoimmune disease) does not anticipate a specific disclosure (uveitis), hence, Claims 9 and 10 are to be considered novel over the cited reference.

Separately rejected is claim 11, the rejection based upon the same reference but the argument being the applied reference is suggestive of the claimed subject matter, namely method of treating a human patient. The Official Action argues that the fact that beneficial results may have been obtained on female mice with polyarthritis, the article suggests it would be "useful as a therapeutic agent in clinical medicine" which the Official Action further asserts that "one of ordinary skill in the art would reasonably expect [the active material] to act as an immunosuppressant in humans suffering from arthritis". Applicants disagree with this rejection and the argument in support of it.

Again applicants repeat that Mistrello et al. teach the immunosuppressive profile of the compound used in the method of the present invention and its application in the treatment of heterologous skin transplantation, which isn't an autoimmune disease. On the contrary, the *in*efficacy of the compound in treating rheumatoid arthritis is reported in this reference.

This means that Mistrello et al. clearly indicate that the compound is effective as immunosuppressant in certain situations (heterologous skin transplant), but is not effective in treating autoimmune diseases. According to Mistrello et al.'s results, the compound is effective in inhibiting the formation of auto-antibodies against rat erythrocytes. This information is not sufficient to establish that the compound is effective in treating autoimmune diseases.

The person skilled in the art has no clear guidance to treat uveitis with the claimed method.

Taking the factual enquiries depicted in the Office Action, applicants offer the following points:

1. The scope and contents of the prior art:

a. The scope of Mistrello et al. is to suppress immune response in case of skin heterologous transplant with the compound used in the present invention; Mistrello et al. shows the compound is ineffective in the treatment of autoimmune diseases;

2. Ascertaining the differences between the prior art and the claims a issue:

a. The present invention treats an autoimmune disease, specifically uveitis with the same compound of the state of the art. The difference resides in the disease treated;

3. Resolving the level of ordinary skill in the pertinent art:

a. The person skilled in this art is a medical practitioner and is guided in his or her action by the teaching of the art, which must be clear and promising of the expected result. Benefit to the patient must be the expectation of the treatment. In this particular case, the art is medical art and the skilled practitioner will not be inclined to experimentation or attempts in treating a human, such as in case of claim 11, without clear indication and instruction from the art. This skilled person bears the responsibility of treating a disease in a human; therefore, unpredictable tests will not be tried. Of more concern, when the state of the art teaches that the treatment in not effective, such as in the case of Mistrello et al. No rational medical practitioner would set out to use in human (or other) therapy a product reported and documented to be ineffective for the therapeutic object intended to be remedied.

4. Considering objective evidence present in the application indicating obviousness or non obviousness:

a. The subject application shows objective evidence by means of a practical example. Therefore, it is totally unexpected and surprising that a compound which was proved to be *in*effective in the treatment of an autoimmune disease showed efficacy in the treatment of uveitis, an autoimmune disease.

In view of the above, Applicants respectfully ask the Examiner to withdraw the standing rejections and proceed with allowance of the claims.

For the above reasons it is respectfully submitted that the claims of this application define novel and inventive subject matter. Reconsideration and allowance are solicited.

Respectfully submitted,

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